CHARTER DoD PHARMACY AND THERAPEUTICS COMMITTEE

I. AUTHORITY

The National Defense Authorization Act for Fiscal Year 2000, Public Law 106-65, Oct. 5, 1999, section 701, amended chapter 55 of Title 10, U. S. Code, by inserting after section 1074f a new section, 1074g, entitled "Pharmacy Benefits Program." Under section 1074g(b), the Secretary of Defense is required to establish a Pharmacy and Therapeutics Committee for the purpose of developing a uniform formulary of pharmaceutical agents, review such formulary on a periodic basis, and make additional recommendations regarding the formulary as the committee determines necessary and appropriate. The committee shall function under procedures established by the Secretary under regulations promulgated to implement this section.

II. DOD PHARMACY AND THERAPEUTICS COMMITTEE

A. GENERAL PROVISIONS:

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee (henceforth, P&T Committee) is responsible for development and maintenance of a uniform formulary. It consists of government members whose primary mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet patients' clinical needs in an effective, efficient, and fiscally responsible manner. The Committee focuses its attention on actions that will encourage the safe and effective use of pharmaceutical agents that will produce the desired outcomes of drug therapy at a reasonable cost to DoD.

B. PROCEDURES:

The uniform formulary shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes. The selection for inclusion on the uniform formulary of particular pharmaceutical agents shall be based on the relative clinical effectiveness and cost effectiveness of the agents in each therapeutic class of pharmaceutical agents.

(1) Clinical Effectiveness: The P&T Committee shall presume a pharmaceutical agent in a therapeutic class is clinically effective and should be included on the uniform formulary. This presumption shall exist unless the P&T Committee finds by majority vote of those voting that the agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other drugs included on the uniform formulary in that therapeutic class. If the P&T Committee makes such finding, the P&T Committee may recommend that the pharmaceutical agent be placed in the non-formulary tier of the uniform formulary.

- (2) Cost Effectiveness: The P&T Committee, in evaluating the cost effectiveness of pharmaceutical agents, shall evaluate the cost of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of the other agents in the class. If the P&T Committee determines by majority vote of those voting that a pharmaceutical agent in a therapeutic class is not cost effective in relation to the safety, effectiveness, and clinical outcome of such agent, the P&T Committee may recommend that the agent be placed in the non-formulary tier of the uniform formulary.
- (3) Basic Core Formulary: The Basic Core Formulary (BCF) is a sub-set of the approved uniform formulary and applies only to military treatment facilities (MTFs). BCF is the minimum formulary that must be available at all MTFs. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion on BCF.
- (4) Extended Core Formulary: The Extended Core Formulary (ECF) is a subset of the approved uniform formulary, and applies only to MTFs. ECF is a list of medications that may be on an MTF formulary, if providers at that MTF require agents from that therapeutic class for the scope of care that is provided at the MTF beyond primary care. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion on ECF.
- (5) All recommendations shall be by majority vote of the voting members participating.

C. <u>DUTIES OF THE DoD PHARMACY AND THERAPEUTICS</u> <u>COMMITTEE:</u>

- (1) Periodically conduct therapeutic drug class reviews.
- (2) Consider the relative safety, effectiveness, cost, and other pertinent factors in recommending pharmaceutical agents to be included on the uniform formulary, BCF, and ECF.
- (3) Recommend an implementation period and medical necessity criteria for all pharmaceutical agents recommended for non-formulary status.
- (4) Identify drugs that are candidates for prior authorization and recommend prior authorization criteria that would be applied across the Military Health System (MHS).
- (5) Identify drugs that are candidates for quantity limits and recommend quantity limits that would be applied across the MHS.

- (6) Evaluate requests for changes to the uniform formulary, BCF and ECF, quantity limits, prior authorizations, and medical necessity criteria from MHS; and utilize standardized processes for handling such requests.
- (7) Consider medical readiness implications pertaining to BCF and ECF issues.
 - (8) Monitor the effectiveness of the MHS drug distribution system.
 - (9) Review MHS pharmacy utilization and cost data.
- (10) Review and approve the contracting strategies and evaluation factors for DoD and joint Department of Veteran Affairs (DVA)/DoD pharmaceutical procurement contracting initiatives, and prospectively identify circumstances in which it would be medically necessary to use a non-contracted drug in lieu of a contracted drug.
- (11) Consider other matters related to the uniform formulary, MHS drug distribution system, and issues involving the safe and effective use of pharmaceutical agents within the MHS.

D. MEMBERSHIP;

The P&T Committee members must have expertise in identifying the medical and pharmaceutical needs of the populations served throughout the MHS. The P&T Committee will have 17 voting members and additional non-voting members as outlined below. A physician selected by the Director, TRICARE Management Activity (TMA) will chair the P&T Committee.

(1) Voting Members:

- (a) Physician Chairman (Health Affairs/TMA)
- (b) Chief, Pharmaceutical Operations Directorate, TRICARE Management Activity (TMA), or designee
 - (c) Director, DoD Pharmacoeconomic Center (recorder)
- (d) The Army, Navy, and Air Force Surgeon General (SG) Internal Medicine specialty consultants or designees
- (e) One Army, Navy, or Air Force SG Pediatric specialty consultant or designee

- (f) One Army, Navy, or Air Force SG Family Practice specialty consultant or designee
- (g) One Army, Navy, or Air Force SG Obstetric/Gynecology specialty consultant or designee
 - (h) One physician or pharmacist from the United States Coast Guard
- (i) The Army, Navy, and Air Force SG Pharmacy Consultant or designee
- (j) One physician or pharmacist from the Department of Veterans Affairs (DVA)
 - (k) One (each) provider at large from the Army, Navy, and Air Force
 - (2) Non-Voting Members:
 - (a) Representative(s) from Defense Medical Standardization Board
 - (b) Representative(s) from the TMA Office of General Counsel
- (c) Representative(s) from the TMA Resource Management Directorate
 - (d) Representative(s) from the Defense Supply Center Philadelphia
- (e) Contracting Officer's Representative(s) from open TRICARE Pharmacy Program purchased care contracts which include the retail and/or mail order venue
 - (f) Representative from the DoD Patient Safety Program
- (3) Voting members should be available to serve on the P&T Committee for a minimum of three years. Members will rotate off the committee after a four year term.
- (4) Each voting member and non-voting member may have a designated alternate who can represent the member, including voting (if representing a voting member), at P&T Committee meetings in the event the member cannot attend.
- (5) Additional subject matter experts may be requested to participate as required to address specific drugs and/or therapeutic classes under review.

(6) The DoD P&T Committee will meet at least quarterly, as scheduled by the Chairman. Meetings will be scheduled far enough in advance to facilitate appropriate scheduling and notice of Beneficiary Advisory Panel (BAP) meetings.

E. <u>SUPPORTING AGENCY:</u>

The TRICARE Management Activity will provide administrative and related support, including the funding of members' travel to Committee meetings, to the P&T Committee.

III. AGENDA & ROUTING OF MINUTES

The agenda will be provided to the P&T Committee members no later than seven days prior to the meeting date. P&T Committee meeting minutes will be forwarded to the Chief, Pharmaceutical Operations Directorate, TMA, no later than 21 days after the meeting. The BAP will be provided opportunity to comment on the P&T Committee's uniform formulary recommendations concerning: 1) placement of pharmaceutical agents within the uniform formulary, 2) any applicable implementation periods, and 3) prior authorization requirements. The P&T Committee minutes, including the Committee's recommendations, along with the comments of the BAP, will then be forwarded to the Director, TMA for final decision.

IV. OWNER

The Chief Medical Officer shall be accountable to the Principal Deputy Assistant Secretary of Defense (Health Affairs) for the performance of the P&T Committee.

V. DURATION OF CHARTER:

The TMA Director will review this charter biennially from the date of approval.

VI. DATE CHARTER IS FILED:

Ellen P. Embrey

MAY 1 3 2009

Deputy Assistant Secretary of Defense (Force Protection Health and Readiness)

Performing the Duties of

Director

(TRICARE Management Activity)